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09/776,936	12/22/1998	Scott Miller	BAYER-0006-P01	8682
23599 7590 08/15/2012 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER KUMAR, SHAILENDRA				
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/776,936  
Filing Date: December 22, 1998  
Appellant(s): MILLER ET AL.

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Csaba Henter  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 7/3/12 appealing from the Office action mailed 2/3/12.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 36 and 39.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

Appellants are claiming solvated form of compound of formula I, which constitutes new matter, and there is nothing in the specification that suggests that appellants have ever intention of claiming such solvated form, or have even mentioned such solvated form in the specification anywhere.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

#### **(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

#### **(8) Evidence Relied Upon**

4,252,951

JACKSON

2-1981

West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365.

Braga, D, " Making crystals from Crystals: a green route to crystal engineering and polymorphism", Chem. Comm., 2005, pp 3635-3645.

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 36 and 39 are unpatentable under 35 USC 112, first paragraph, as lacking adequate written description for the claimed solvates, and being the new matter.

The claims are directed to a compound having the generic structure recited in formula I and method of treating cancer comprising a compound of formula I in a solvated form.. In both claims, there is an explicit recitation that solvates of the compounds are included in the claimed subject matter. In view of this, the solvates of the claims are viewed as a critical element of the claimed subject matter and must, therefore, be described in accordance with the requirements of 35 USC 1121.

In the language of the physical chemist, a solvate of an organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications", Wiley, New York, 1988, pages 358 & 365. With regard to scope, the instant claims cover a wide variety of structurally divergent compounds

and place no limitation on scope of the solvent component of the claimed solvates. Thus, the claimed solvates broadly encompass interstitial solid solutions comprised of any combination of the thousands of compounds within the formula I structure with any solvent molecule that will form a solvate.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within the genus. See MPEP § 2163.

**1[The Guidelines for Written Description state "The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art" (Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices, column 1, page 1105). The Guidelines further state, "[t]he claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement" (at page 1105, center column, third full paragraph). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines Inc.* (CA FC) 41 USPQ2d 1961 (at 1966).]**

In the instant case, there is no teaching directed to solvates of the claimed compounds and the application fails to disclose even a single example of a solvate within the scope of the claims. **Even the specification fails to mention the word "solvate", thus raising the new matter situation.** Therefore, the application clearly fails to provide a representative number of species of the widely divergent subject matter encompassed by the claimed solvates.

Beyond the disclosure of a representative number of species, the written description requirement for a claimed genus may be satisfied through sufficient disclosure of the relevant identifying characteristics of the genus (i.e., structure or other physical and/or chemical properties), by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics (see MPEP 2163 (ii)).

However, it is recognized in the art that the structural features of solvate compounds are highly unpredictable. For example, Jackson et al. state, "solvates, however, are notoriously unpredictable substances. One can not predict what cephalosporin compounds will form solvates, nor the solvents which solvates may be formed" (e.g., see Jackson et al., U.S. Patent No. 4,252,951, column 1, paragraph 5). This is confirmed by Braga et al. (Braga et al., "Making crystals from crystals: a green route to crystal engineering and polymorphism" *Chem. Comm.* 2005, 3635-3645) who state, "while serendipitous polymorphism and solvate formation are very common ... intentional polymorphism is more difficult" (e.g., see page 3640, column 1, paragraph 1; see same paragraph, "it is extremely difficult to predict whether a new species may crystallize from solution with one or more molecules of solvent"). West (*supra*) concurs, stating in the first paragraph on page 365, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional extent".

Viewed as a whole, the art clearly evidences that the relevant identifying characteristics of a solvate (i.e., the structural interaction of the molecules of the compound and solvent to form the interstitial solid solution) are highly unpredictable. Therefore, the description of the structure of a genus of compounds, as in the instant case, does not constitute a description of all solvates that might be formed from the compounds within that genus.

An adequate written description of a solvate requires more than a mere statement that it is part of the invention; what is required is a description of the solvate itself. It is not sufficient to define an invention solely by its principal property (i.e., it is a solvate of the disclosed compound) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any crystalline form of the disclosed compound with that property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. In view of this, the application clearly fails to describe the claimed solvates. **However, not only appellants have not made any solvate, appellants have even failed to mention the word "solvate" in the specification, suggesting that they had no intention of making and claiming the "solvates" and thus raising the new matter situation, apart from the written description requirement.**

#### **(10) Response to Argument**

**Appellants argue that the specification of the present application clearly teaches the concept of solvates by disclosing specific embodiments of combination of compounds of the claims with solvents. The Examiner disagrees. A mere fact that appellants have failed to mention the word "solvate" in the specification, claiming solvates is essentially a new matter and clearly lack the written description for that matter. Appellants point out to the various solvent system and suggest that solvates have been formed. Merely putting a compound in the solvent does not form solvate. It forms solution.**

**Appellants admit that the term "solvate" does not explicitly appear in the disclosure, see bottom of page 3 of the brief. Appellants point out to the crystals formed on page 61. Crystals itself does not necessarily suggest that solvate has been formed. Appellants point out to Braga and West suggesting that solid solutions are very common in crystalline material. This is true if the intention is of making solvate. However, in the instant case, claiming solvate was beyond the scope of the instant specification and claiming solvate is a new matter.**

**Appellants point out to various patents suggesting that solvates of the urea compounds were known by those of ordinary skill in the art. None of the patents cited have made any solvate and US'4,379,786 is simply suggesting that solvate can be made. This does not mean that since all other patents are suggesting that solvate can be made, instant application automatically gets the patent for the solvate, especially when claims to solvate is a "new matter". Appellants' arguments that since compounds and solvents are embodied in the instant specification, solvates are automatically known. Solvate chemistry is not as simple as appellants are describing. As evidenced by West and Braga references cited, solvate formation is a tedious process. Thus it is clear that claiming solvate is a new matter for claims 36 and 39 and also lack adequate written description for the claimed solvate.**

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

//SHAIENDRA KUMAR/

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